NEWCLIP-TECHNICS

K130774

JUN 19 2013

4. 510 (k) Summary for Universal Distal Radius System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following 510(k) summary is submitted for the Universal Distal Radius System.

Summary preparation date: February 11, 2013

1. Submitter:	**Contact Person:**
NEWCLIP TECHNICS P.A. de la Lande Saint Martin 45 rue des Garottières F-44115 Haute-Goulaine - France Telephone: (33) 2 28 21 37 12	J.D. Webb The OrthoMedix Group, Inc. 1001 Oakwood Blvd Round Rock, TX 78681 Telephone: 512-388-0199

2. Trade name:	Universal Distal Radius System
Class:	II
Product code:	HRS/HWC
Common Name:	Plates for distal radius Screws for distal radius
Classification Name:	Plate, Fixation, Bone (21 CFR part. 888.3030) Screw, Fixation, Bone (21 CFR part. 888.3040)

3. Predicate or legally marketed devices which are substantially equivalent:

- The Distal Radius Locking Plating System of Newclip Technics (K061917).
- The Clavicle Locking Plating System of Newclip Technics (K100944).
- Synthes Locking Distal Radius Plating System (K102694).
- Acumed Congruent Bone Plate System (K102998).
- Medartis AGAPTUS® 2.0 Radial Head System (K090053).

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4. Description of the device:

The Universal Distal Radius System consists of a range of plates and screws for distal radius surgery. Each device is manufactured from titanium and can be color anodized. The Universal Distal Radius System will be provided non-sterile for steam sterilization by health care professional's prior use, or provided sterile by gamma sterilization.

Materials:

Titanium alloy Ti-6Al-4V ELI (conform to ASTM F 136-02a and/or ISO 5832-3).

Function:

The implants of Universal Distal Radius System are indicated for fixation of intra and extra-articular fractures as well as distal radius osteotomy.

Change from Predicate:

This Special 510(k) is submitted in order to gain clearance for plates that are substantially equivalent to the predicate and additional screws.

5. Substantial equivalence claimed to predicate devices:

The Universal Distal Radius System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performance.

6. Intended use:

The Universal Distal Radius System is intended for fixation of intra and extra-articular fractures as well as distal radius osteotomy

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7. Non-clinical Test Summary:

The following tests were conducted:

- Comparative compression and flexion test on plates.

8. Non-clinical Test Summary:

No clinical studies were performed.

9. Conclusions Nonclinical and Clinical:

The Universal Distal Radius System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 19, 2013

NEWCLIP TECHNICS
% The OrthoMedix Group, Incorporated
Mr. J.D. Webb
Official Correspondent
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K130774
Trade/Device Name: Universal Distal Radius System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: May 22, 2013
Received: May 24, 2013

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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3. INDICATIONS FOR USE

510(k) Number (if known): K130774

Device Name: Universal Distal Radius System

Indications for Use:

The Universal Distal Radius System is intended for the fixation of intra and extra-articular fractures as well as distal radius osteotomy.

Prescription Use ___X___ AND/OR Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices